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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,198	03/09/2007	**Inderjit Singh**	MESC:013US	3351

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,198	SINGH, INDERJIT	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/2/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner notes at the outset the present application is subject to restriction, sent herewith. Although the application is not yet under examination on the merits, claim 1 is seen as comprising the term "preventing and treating". Unless the invention is capable of 100% prevention as shown by testing (e.g. like a vaccine), the term "preventing" will be subject to rejection under 35 USC 112 1st enablement. Applicant may wish, in response hereto, to preemptively amend the claims to delete all reference to "preventing", should Group I be elected (or Group II if term in these claims as well); to further advance prosecution on the merits ahead of schedule.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-32, drawn to a method of preventing or treating ANY inflammatory disease or condition comprising ANY glutathione donor and one of:

5-amino 4-imidazolecarboxamide ribotide(AICAR), a 3-hydroxy-3-methylgluatryl-coenzymeA (HMG-CoA) reductase inhibitor, D-threo-l-Phenyl-2-decanoylamino-3-morpholino-l-propanol HC1 (D-PDMP), or 1,5- (butylimino)-1,5-dideoxy-D-glucitol (Miglustat), or a derivative thereof.

II. Claims 33-61, drawn to a composition comprising ANY glutathione donor and one of:

5-amino 4-imidazolecarboxamide ribotide(AICAR), a 3-hydroxy-3-methylgluatryl-coenzymeA (HMG-CoA) reductase inhibitor, D-threo-l-Phenyl-2-decanoylamino-3-morpholino-l-propanol HC1 (D-PDMP), or 1,5- (butylimino)-1,5-dideoxy-D-glucitol (Miglustat), or a derivative thereof.

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

Peptide Markush Group-Lack of Unity

The inventions are independently drawn to a composition or method preventing or treating ANY inflammatory disease or condition comprising ANY glutathione donor and one of:

5-amino 4-imidazolecarboxamide ribotide(AICAR), a 3-hydroxy-3-methylgluatryl-coenzymeA (HMG-CoA) reductase inhibitor, D-threo-l-Phenyl-2-decanoylamino-3-morpholino-l-propanol HC1 (D-PDMP), or 1,5- (butylimino)-1,5-dideoxy-D-glucitol (Miglustat), or a derivative thereof.

The technical feature that must be present throughout the group is ANY glutathione donors.

However, since glutathione donors are well known in the art (no reference needed), such does not constitute a “special” technical feature and thus the groups lack unity of invention.

Requirement for a Single Inflammatory Disease or Condition as the Invention

In response hereto, Applicant must further elect a single inflammatory disease or condition as the 'invention', since a search of any is not coextensive (and subject to different issues under 35 USC 112 1st/2nd) and thus constitutes an undue search burden. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

Requirement for a Single Caspase Inhibitor Election as the Invention

Each glutathione donor, structurally, constitutes a distinct compound and thus any invention comprising the same. A search of any caspase inhibitor, without identification of a core structure present in each that may be coextensively searched, presents an undue search burden. Thus, for Groups I-IV Applicant must elect a single caspase inhibitor as the invention. Additionally as to Group IV, Applicant must elect a single compound from the other compounds that may be included, under the same rationale, as the compound of the invention, to which such will be searched/examined, if elected. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

NOTE: The Examiner is, however, wiling to search the elected glutathione donor with ANY of the following other 5 compounds claimed, as constituting the complete composition of the invention, for use therewith: 5-amino 4-imidazolecarboxamide ribotide(AICAR), a 3-hydroxy-3-methylgluatryl-coenzymeA (HMG-CoA) reductase

inhibitor, D-threo-l-Phenyl-2-decanoylamino-3-morpholino-l-propanol HC1 (D-PDMP), or 1,5- (butylimino)-1,5-dideoxy-D-glucitol (Miglustat), or a derivative thereof.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 9/29/2009
/Maury Audet/
Examiner, Art Unit 1654
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